



National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
P.O. Box 18070
Pittsburgh, PA 15236

Procedure No. CET-PAPR-STP-CBRN-0553

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DETERMINATION OF LABORATORY RESPIRATOR PROTECTION LEVEL (LRPL)
QUANTITATIVE, MEDIUM FLOW, DEEP PROBE, CORN OIL, FIT FACTOR PERFORMANCE
TEST FOR

CHEMICAL, BIOLOGICAL, RADIOLOGICAL AND NUCLEAR (CBRN) LOOSE-FITTING
POWERED AIR-PURIFYING RESPIRATOR (PAPR) STANDARD TESTING PROCEDURE (STP)

1. PURPOSE:

- 1.1. This test establishes the procedures for determining respiratory protection factors provided by CBRN PAPR requirements submitted for New Approval, Extension of Approval, or examined during certified product audits, meet the minimum certification standards set forth in this STP as prescribed in 42 CFR, Part 84, Subpart G, Section 84.63(a)(c)&(d); Federal Register, Volume 60, Number 110, June 8, 1995 and the *Statement of Standard for Chemical, Biological, Radiological, and Nuclear (CBRN) Powered Air-Purifying Respirator (PAPR)*.
- 1.2. This STP is used to test CBRN loose-fitting PAPR, which hereafter may be referred to as PAPR against corn oil aerosol while worn by a human test subject breathing in a dynamic eleven exercise-specific sequence. Aerosol quantifying instrumentation remotely senses internal and external corn oil concentrations via the attachment of tubing to the specific oral/nasal probe mounted in the tested PAPR.
- 1.3. The requirement for this STP is to ensure that all PAPR, seeking NIOSH certification for protection against CBRN hazards have:
 - 1.3.1. Good self-donning characteristics, under controlled laboratory observation that can accommodate a wide variety of facial sizes and shapes, neck sizes, and head sizes.
 - 1.3.2. User's instructions for PAPR size selection and donning that are easily understood, applicable to all submitted components and are compliant at the time of issuance of the NIOSH approval letter.
 - 1.3.3. Achieved a pass or fail result based on completing all eleven LRPL exercises as determined by appropriate pass criteria per class of respirator.
 - 1.3.4. Been evaluated on a complete test subject panel having facial sizes and shapes, neck sizes, and head sizes that approximate the distribution of facial sizes / shapes, neck sizes, and head sizes of the general applicable statement of standard user population. Quantities of required test subjects and sample respirators are described in Appendix A, LRPL Test Sample Quantities for PAPR with Loose-

Approvals:	1 st Level	2 nd Level	3 rd Level

Fitting Hoods.

- 1.3.5. The aerosol measurement system is required to have a minimum limit of detection $\leq 0.0002 \text{ mg/m}^3$ to accurately measure protection factors up to 100,000 for the specified chamber exposure conditions of 20 to 40 mg/m^3 with a geometric standard deviation less than 2.0.

2. GENERAL

- 2.1. This document describes the Determination of LRPL Quantitative, Medium-Flow, Deep Probe, Corn Oil, Fit Factor Performance Test for CBRN Loose-Fitting PAPR in sufficient detail that a team of persons knowledgeable in the appropriate technical field can select equipment with the necessary resolution, conduct the test, and determine whether or not the PAPR passes the specified test. The procedure is designed to rigorously test the evaluated PAPR on a human test subject as a dynamic respiratory protective system and generate repeatable, independent pass or fail results under defined laboratory conditions.
- 2.2. This STP shall be used to test CBRN PAPR for satisfactory LRPL performance.

3. TEST EQUIPMENT / TEST ITEMS/ HUMAN SUBJECTS

- 3.1. The list of necessary test equipment and materials follows:
- 3.1.1. Corn oil - 99%. Commercial Product Name; Maise Oil, Maydol, Mazola Oil, Maize Oil. Corn oil utilized must comply with Chemical Abstract No. 8001-30-7 prior to test commencing. Material Safety Data Sheets (MSDS) for the type of corn oil used must be posted for review by all test subjects and laboratory personnel in accordance with EPA Right to Know regulations, applicable OSHA HAZCOM requirements and this STP.
- 3.1.2. Environmental test chamber and plenum system or equivalent. The chamber shall be designed so that the individual(s) performing LRPL testing are visible at all times while in the chamber. The chamber design must meet local fire codes for enclosed spaces including an entry vestibule designed to allow safe entry and exit from the chamber with minimal disturbance to both aerosol concentration and uniformity. The vestibule shall be large enough to accommodate entry vestibule door swing and eight test subjects while the main entry chamber door is closed. The test chamber shall be capable of maintaining corn oil aerosol spatial uniformity to within ± 10 percent in the vicinity of the human test subject wearing the respirator being tested. The challenge aerosol concentration shall not vary as a function of time more than ± 10 percent over the duration of a single test (approximately 10-15 minutes). The aerosol challenge shall be characterized continually by a known quantitative system to verify that the aerosol is within specified parameters as detailed in Section 3.1.4. The interior of an equivalent uncharged corn oil chamber is shown in Figure 1. An example of a charged corn oil chamber is provided in Figure 2.



Figure 1. Uncharged Corn Oil Test Chamber



Figure 2. Charged Corn Oil LRPL Chamber

- 3.1.3. Environmental Control System or equivalent. The Environmental Control System shall be capable of maintaining 20-80% RH \pm 5% and 65-95°F \pm 5°F as normal operating range of conditions (ambient target) for LRPL tests conducted ideally at 70°F and 50 % RH. An example of an equivalent environmental control system, the DataAire Model DAP-2 Environmental Control System, is shown in Figure 3.



Figure 3. Environmental Control System

- 3.1.4. Aerosol Measurement System or equivalent: The aerosol measurement system(s) shall be used to measure the individual aerosol challenge and leak concentrations per sampling point and accurately generate quantitatively measured LRPL factors of up to and including 100,000. An example of a LRPL aerosol measurement system is the TSI Rear Light Scattering Laser Photometer, model 8587, with applicable software, as indicated in Figure 4. Additional photometers used in determining before, during and after chamber ambient test concentrations and Mass Median Aerodynamic Diameter (MMAD) spatial distribution for compliance are the TSI model 8520, DustTrak Aerosol Monitor and the Scanning Mobility Particle Sizer (SMPS). Model 8587 operates by measuring voltage proportional to aerosol concentration. The capability of the photometer to accurately measure protection factors of at least 100,000 is dependent on the photometer's limit of detection and the aerosol chamber concentration. Mathematically calculated, at the chamber conditions of 20 mg/m³ (the lower limit of the specified CBRN concentration range) the photometer system has a minimum limit of detection of $(20 \text{ mg/m}^3 / 100,000) = 0.0002 \text{ mg/m}^3$ and can accurately measure a protection factor of 100,000. The photometer is able to accurately and reliably measure 0.001% of the chamber concentration when the chamber is at 20 mg/m³. Mathematically calculated: $0.0002 \text{ mg/m}^3 / 20 \text{ mg/m}^3 \times 100\% = 0.001\%$.



Figure 4. Aerosol Measurement System

- 3.1.5. Aerosol Generator or equivalent. The Aerosol Generator shall be capable of maintaining 20 to 40 mg/m³ corn oil challenge aerosol concentrations with a MMAD of 0.4 to 0.6 µm in the test chamber. The geometric standard deviation shall be less than 2.0. The equipment shall be capable of operation with out using recycled air. An example of an Aerosol Generator system, the MSP Model 2045 High Output Aerosol Generator, is shown in Figure 5.

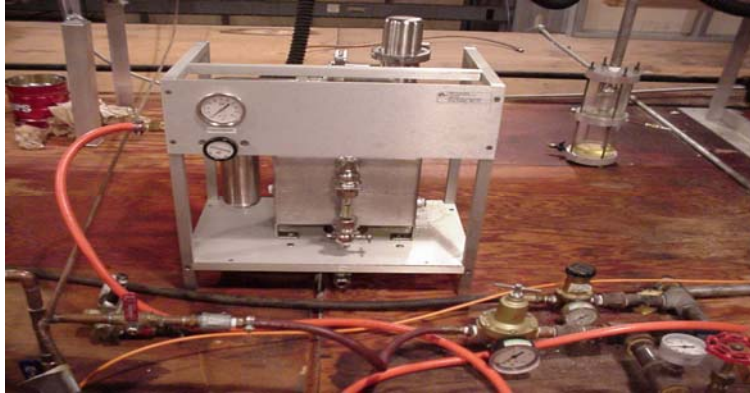


Figure 5. Aerosol Generator

- 3.1.6. Chamber Concentrations. The chamber aerosol concentration shall not vary as a function of time more than ± 10 percent over the duration of a single test trial (approximately 15 minutes). The test chamber shall be capable of maintaining spatial uniformity within ± 10 percent in the vicinity of the respirator being tested. An example of an instrument to verify spatial uniformity and chamber concentrations is the TSI Dust Trak photometer shown below in Figure 6.



Figure 6. Dust Trak Photometer

- 3.1.7. Communications. A means of providing two-way communication between the test subject(s) and the test conductor(s) is required. Non-verbal communication such as hand and arm signals, clear line of sight, and other non-verbal means from test subjects inside the test chamber to attending laboratory technicians outside the chamber meets this requirement provided the test subjects and the test proctors can clearly see each other and communicate with non-verbal signals. Electronic audio communications (chamber loudspeaker) from laboratory technicians to test subjects is also required to ensure test subjects can clearly hear when to start and stop the test exercise regimen.
- 3.1.8. Facial/Neck Size Measurement; Calipers, Measurement Tapes, or equivalent. Calipers and measurement tapes shall be used to measure anthropometric variables for subject placement in the CBRN PAPR LRPL Test Panels (Appendix B - LRPL Test Panels for PAPR with Loose-Fitting Hoods). Examples of calipers are sliding measurement calipers, Seritex Model GPM 104, 0-200 mm length, or spreading measurement calipers, Seritex Model GPM 106, 0 – 300 mm width. Measurement tape shall have millimeters as the smallest increment of measure. Figure 7 depicts examples of Facial/Neck Size Measurement Calipers. Figure 8 is an example of software written in Visual Basic to manage the panel test measurements and placement of subjects.

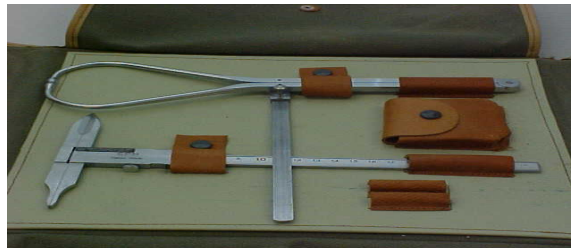


Figure 7. Facial/Neck Size Measurement Calipers

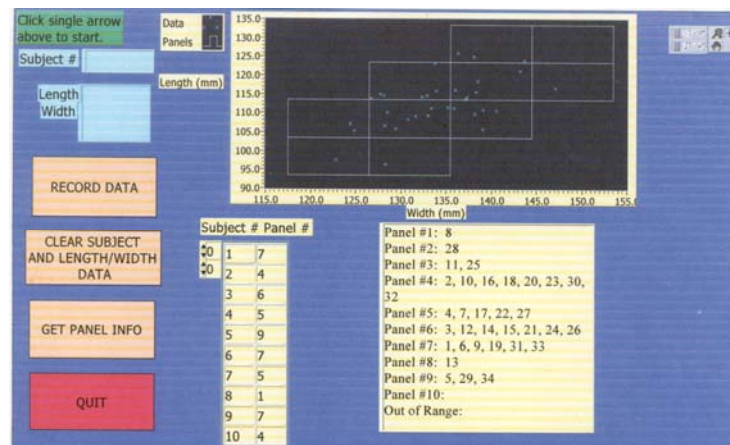


Figure 8. Sample LANL Panel Calibration Software

- 3.1.9. Tubing. Tygon tubing (1/4-inch ID) and connectors used to mate the PAPR probe to photometers.
- 3.1.10. Facepiece Direct Probe Tygon Tubing Connector. Figure 9 illustrates a close-up view of a Probe Tubing Connector used to connect the interior of a PAPR to the aerosol sampling system. The connector is fabricated from stainless steel and is equivalent to a 1/4-28 all-thread rod that is fully bored through the center with a 0.748-inch-in-diameter by 0.16-inch-thick flange attached on one end. The fasteners used to fasten the sealing surfaces are 1/4-28 nuts, metal washers, and rubber washers. The connector length is dependent on the distance from the exterior surface to the interior surface of the PAPR. Tygon tubing, 1/4-inch in inner diameter, is pushed over the 1/4-28 all-thread rod on the facepiece exterior side only and held in place by a friction fit. The tygon tubing is connected on the other end to the aerosol sampling system. Figure 10 shows two mechanical drawings depicting the dimensions for the connector required for LRPL direct probe sampling. Figure 11 illustrates a frontal exterior view and Figure 12 a side view of a PAPR probed for LRPL sampling.



Figure 9. Probe Tubing Connector

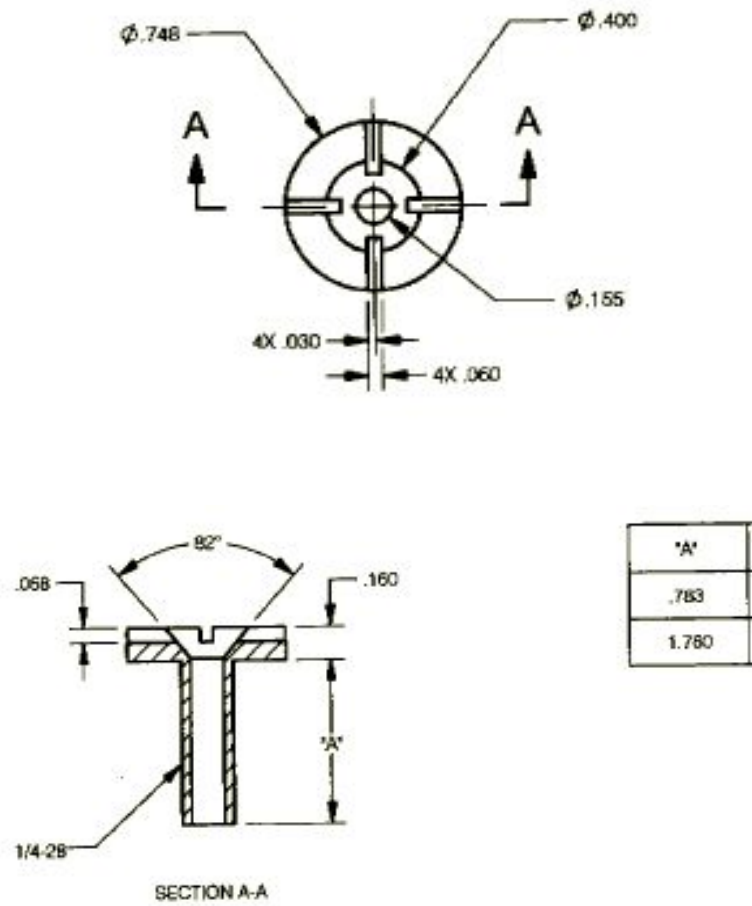


Figure 10. Probe Tubing Connector, two drawings (unit of measure - inch)



Figure 11. Frontal Exterior View of Sample LRPL Probed PAPR



Figure 12. Side View of a Sample LRPL Probed PAPR

3.1.11. Corn Oil Particle Size Distribution Aerosol Monitor or equivalent. Scanning Mobility Particle Sizer (SMPS), TSI model # 3934 determines the 0.4 to 0.6 MMAD particle size distributions. This determination is required to be performed weekly. Figure 13 shows an SMPS.

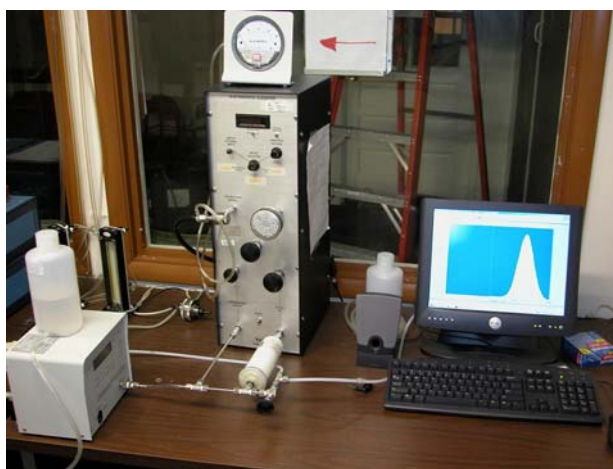


Figure 13. Scanning Mobility Particle Sizer

3.2. Required PAPR Test Items: Each applicant shall provide the maximum number of PAPR units of production quality, in the NIOSH agreed configuration, of each specified size configuration specified in Appendix A. User's instructions for self-donning and system attachments or other hardware are required for each PAPR submitted for testing. Test factors such as weight of accessories, weight of critical components, type of head harness used and identical LAT configuration tested must be adhered to.

- 3.2.1. Blower On Mode for PAPR with Loose-Fitting Hoods; up to 25 PAPR with Loose-Fitting Hoods are required if one universal size is tested, 29 PAPR with Loose-Fitting Hoods if two sizes (14 Small/Medium and 15 Medium/Large) are tested, and 38 PAPR with Loose-Fitting Hoods if three sizes (10 Small, 17 Medium, and 11 Large) are tested. Additional size configurations are also possible; in these cases, NIOSH will determine the panel size, applicable anthropometric measurement ranges, and PAPR with Loose-Fitting Hoods test quantity.
- 3.2.2. Blower Power; Provide additional batteries if batteries are disposable or recharging capabilities if batteries are not disposable.

3.3. Human Factors:

- 3.3.1. Test Subjects. The minimum and maximum number of test subjects for each size configuration are specified in Appendix A. All procedures and requirements specified in the NIOSH Human Subject Review Board (HSRB) Protocol HSRB-03-NPPTL-04XP entitled, "Determination of LRPL for RPD Submitted for NIOSH Certification" shall be followed and met. Informed consent will be obtained from each volunteer upon completion of the Volunteer Agreement Affidavit and Volunteer Agreement Affidavit Explanation contained in Protocol No. HSRB-03-NPPTL-04XP. The test subjects shall be required to complete a Health History Questionnaire as part of the Volunteer Agreement Affidavit Explanation contained in Protocol No. HSRB-03-NPPTL-04XP. Electronic caliper, manual caliper, and measuring tape measurements shall be used to determine facial/neck/head sizes for subject panel placement and assignment of PAPR size.
- 3.3.2. Test Administrator(s). Shall have successfully completed the CDC/ATSDR Scientific Ethics Training, the DHHS/NIH Human Participant Protections Education for Research Teams or an equivalent NIOSH sanctioned course. Note: The NIOSH Human Subject Review Board will determine if specific courses not stated above are equivalent. It is the responsibility of the testing laboratory principal investigator to ensure all appropriate scientific ethics training requirements are met prior to testing.

4. TESTING REQUIREMENTS AND CONDITIONS:

- 4.1. Live Agent Test. The successful completion of NIOSH/NPPTL designated Live Agent Test (LAT) performance requirements must be demonstrated sufficiently before LRPL testing commences in parallel or sequential processes.
- 4.2. Calibration. Prior to beginning any testing, all measuring equipment utilized for final measurements as part of this testing must have been calibrated within the preceding 12 months, or as specified by the equipment manufacturer, using a method traceable to the National Institute of Standards and Technology (NIST). Equipment calibration records

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shall be available for examination by NIOSH or its representative at each testing facility. Laboratory technicians will ensure required calibration methods and actions are in place prior to the conduct of testing. A statement that all test equipment has been calibrated in this manner in the preceding 12 months shall be attested by the lab technician on each NIOSH test report.

- 4.3. Safety. Normal laboratory safety practices must be observed. This includes safety precautions described in the current NIOSH Bruceton Research Center Laboratory Safety Manual or site-specific procedures applicable to health and safety requirements.
- 4.4. Certification Inventory. Test facility personnel will confirm with NIOSH that the PAPR model submitted for LRPL testing is the same model and configuration as submitted under the NIOSH application for certification with all required accessories per the manufacturer and that this model has been successfully live agent tested or is in the process of being live agent tested by NIOSH. Part number inspection, location and referencing must be accurate and complete before testing begins. It is the testing laboratory's responsibility to determine what the best method is to manage this. For labs that do not have access to NIOSH DEIMS server capabilities, an on-site physical inspection of incoming respirator hardware is highly recommended. Any accessories that effect form, fit, function (weight, types of head harness etc...), or provide a perceived, implied, or actual protective quality, shall be installed on the PAPR prior to actual LRPL testing. NIOSH/NPPTL Statement of Standard "Guidelines for Identification of Test Configurations for Exposure to GB/HD and Part Number Change Guidelines", dated March 7, 2003, provides guidance on the current testable configuration for LAT and that configuration should match the configuration used for LRPL testing. Facility personnel are required to keep a certification equipment inventory log, prior to LRPL testing commencing, while in progress, and upon termination. Individual manufacturer's PAPR equipment stocks are required to be separated and, if multiple manufacturers are on the test site the same day, hardware should be covered or out of direct visual inspection by competing manufacturers, applicants or customers.
- 4.5. Probing. Each PAPR shall be probed and verified functional prior to issue to test subjects by lab personnel for purposes of measuring concentrations of corn oil at the oral/nasal zone in accordance with Section 3.1.10 of this STP. This functional check may include test personnel donning the PAPR, checking the fit, and performing several trials in the test chamber. For those PAPR without oral/nasal cups defining the breathing zone, the sampling probe must still extend into the oral/nasal zone as per Para 3.1.10 of this STP. The LRPL test facility administrator or his staff probes the PAPR to be tested. The respirator manufacturer may elect to witness the probing with prior approval from NIOSH. As deemed necessary by NIOSH and the LRPL test facility, the effectiveness of the probing may be verified by a manufacturer's method prior to the actual LRPL corn-oil testing. The PAPR sampling location is in the breathing zone. The optimum sampling probe position for the breathing zone is approximately 1/4 inch from the skin at the point of quadrilateral symmetry of the mouth and nose (i.e. midway between the nose and upper lip). The exact final position of the sample probe will depend upon the design of the PAPR being evaluated. Destructive probing techniques shall be used unless otherwise approved by NIOSH.

- 4.6. User's instructions. Prior to conducting the test, the User's Instructions provided with the test equipment shall be reviewed by the test facility personnel and the test subjects. Test subjects will be instructed by the principal investigator or a facility representative in the areas of manufacturer's size selection criteria, donning, doffing, and other fitting procedures for the PAPR, in order to represent any training prescribed or offered by the manufacturer's User's Instructions. Any clarifications or supplemental instructions provided by manufacturer representatives at the time of certification inventory, during the test, or after the test must be NIOSH reviewed prior to incorporation into revised User's Instructions before final NIOSH approval is granted.
- 4.7. Self Donning and Doffing. Each test subject shall perform an unassisted donning and doffing of the PAPR in accordance with the manufacturer's User's Instructions prior to entering the corn oil LRPL chamber. Each test subject conducting self-donning and self-doffing under supervision of test facility personnel is permitted time to make the appropriate adjustments to the PAPR until they are satisfied that they are wearing the PAPR in compliance with the manufacturer's User's Instructions prior to entering the chamber. Self-Donning and self-doffing relies on the clarity of the user's instructions addressing, if applicable based on design, such issues as head harness pull-tab sequence, blower activation, proper seating of oral/nasal cups, ergonomics of donning and doffing, and proper orientation of other relevant PAPR components.
- 4.8. Air Flow Sampling. Air shall be sampled out of the respirator oral/nasal zone at a rate of 2.2 ± 0.2 Lpm. The method in which the sampling probe is installed shall not interfere with the PAPR performance and shall minimize sampling biases. The aerosol challenge shall be characterized continually by a known quantitative system to verify that the aerosol is within specified parameters.
- 4.9. LRPL Exposure Chamber Conditions:
- 4.9.1. Temperature Range = 68-80 °F
- 4.9.2. Relative Humidity Range = 50 ± 10 %
- 4.9.3. Corn Oil Challenge Concentration = $20-40 \pm 2.0$ mg/m³
- 4.9.4. The oxygen level shall be at least 20% for the duration of each test.

5. PROCEDURE:

Note: Review the manufacturer's operation and maintenance manuals of test equipment for calibration instructions, operational use, and maintenance procedures prior to commencing this STP.

- 5.1. General. This procedure describes the LRPL performance test for ensuring that the protection factor provided by the CBRN PAPR meets or exceeds the requirements defined in the Statement of Standard for CBRN PAPR. Refer to the current version of the PAPR Statement of Standard for further explanation of the LRPL requirements. This procedure describes the required human subject sample size, test equipment, data

collection methods, human use protocol requirements, and the specific performance requirement for the PAPR being tested.

5.2. Number of Test Samples.

- 5.2.1. Each applicant shall provide the maximum number of PAPR systems that are of production quality, in the NIOSH agreed configuration, as described in Appendix A.
- 5.2.2. All PAPR systems shall be individually numbered with an indelible pen or tagged in a sequence such that the number can be correlated to the NIOSH application number (TN), manufacturer, and administrative sequence number for tracking throughout the LRPL test process.
- 5.2.3. The administrative sequence numbers are replicated in the test summary data sheets and indicate product performance per the stated requirement.

5.3. Test Equipment and Chamber Set-Up:

- 5.3.1. Test facility staff will install the sampling probe, in accordance with Section 4.6 of this STP, in each PAPR submitted under the applicable NIOSH TN and verify the integrity of probes before physical testing is begun. A short length of tubing will then connect the sample probes in the PAPR to the aerosol detector unit.
- 5.3.2. In accordance with local operational standard procedures, add corn oil to the aerosol generators and allow 15 minutes for the chamber concentration to stabilize.
- 5.3.3. Electronic or manual calipers with equivalent accuracy to the Seritex Model GPM 104, 0-200 mm length, or spreading measurement calipers, Seritex Model GPM 106, 0 – 300 mm width, shall be used for facial length and width measurements. Measurement tape shall be used for head and neck circumference measurements. Measurement tape shall have millimeters as the smallest increment of measure.
- 5.3.4. Inadequate test probing examples are, but are not limited to probes that: 1) do not clearly enter the oral/nasal breathing zone, 2) penetrate just the eye lens without penetrating the oral/nasal cup, 3) penetrate through a PAPR molded seam, or 4) enter the oral/nasal cup but are blocked by internal respirator parts.
- 5.3.5. All test equipment operating data shall be recorded and maintained as part of the test records.

5.4. Conducting the LRPL Test:

- 5.4.1. Panels: Test subjects shall be selected to cover the applicable cells based on the component design of the PAPR and manufacturer sizing guidance. The LRPL Test Panel for PAPR with Loose-Fitting Hoods are referenced in Appendix B.

The anthropometrical measurements to be taken are: 1) face length (Menton-Nasal Root Depression, also called Menton-Sellion); 2) face width (Bizygomatic diameter); 3) neck circumference: at the level of the infrathyroid landmark (Adam's apple) and measured perpendicular to the long axis of the neck; and 4) head circumference: the maximum circumference of the head just above the ridges of the eyebrows (supraorbital ridges) and the attachment of the ears. To measure head circumference, the subject looks straight ahead, the plane of the tape will be higher in the front than in the back and the sides should be parallel, and enough tension is exerted to compress the hair.

- 5.4.2. Size Assignment: Anthropometric sizing determines what size PAPR is issued to the test subject, if multiple sizes are available. For subjects that are of overlapping size assignment categories, for example Small and Medium, manufacturer procedures for evaluating respirator fit, if specified in the product's User's Instructions, will be performed to determine which size is assigned. The best-fitting size, as determined by these procedures, will be assigned. Subjects that do not pass the fit criteria specified in the product's User's Instructions are not authorized to be used as subjects for the LRPL corn-oil test. All LRPL corn-oil passing or failing test results will be considered valid (unless otherwise determined by NIOSH through post-test failure analysis) for those subjects that have passed the fit criteria specified in the product's User's Instructions. For those cases, where a test subject is rated for a dual size category (for example, Medium and Large), the use of expert sizing by test facility personnel is required to determine what size is initially tested. If test subjects fail their initially assigned size category twice, test facility personnel are authorized to resize the individual if panel test subjects availability is in demand.
- 5.4.3. Pre-screening test subjects with a Portacount shall only be performed if the user's instructions mandate such quantitative pre-test fit testing. If the user's instructions recommend or suggest quantitative pre-test fit testing, only the user's seal check as described in the user's instructions shall be performed.
- 5.4.4. Trials: Each LRPL subject shall perform a total of 2 trials with each trial consisting of evaluation of the breathing zone. Each trial begins with a self-donning and consists of the eleven LRPL exercises.
- 5.4.5. Training. Procedures for donning, doffing, trouble shooting, head harness tightening, and accessory interfacing based on the manufacturer's NIOSH recognized User's Instructions shall be taught to test subjects by test facility personnel. Any clarifications or supplemental instructions provided by manufacturer representatives at the time of certification inventory, during the test, or after the test must be NIOSH reviewed prior to incorporation into revised user's instructions before final NIOSH approval is granted. Manufacturers may request the opportunity to observe LRPL testing of their equipment, with prior notification to NIOSH/NPPTL. The PAPR to be tested shall be assigned to clean-shaven test subjects by trained test facility personnel. The PAPR to be tested will also be used for practicing donning/doffing. After initial donning instruction and eleven exercise demonstrations, each test subject shall practice

donning and doffing for 15 minutes under the guidance of test facility personnel. Following the donning and doffing training, each test subject shall practice wearing the PAPR continuously for 15 minutes to attain acclimatization and familiarity.

5.4.6. Ready Line. After the test subjects have completed applicable administrative paperwork, have been trained, and performed practice donning/doffing, they are moved to the ready line in groups of eight or an equivalent number based on the number of operational photometer test input lines.

5.4.7. Respirator and Sampling Line Purge: Following respirator connection to the photometer sampling line, and prior to beginning the eleven test exercises, the sample line will be purged for 15 seconds at a flow rate of 13 to 14 Lpm.

5.4.8. Entry and Exit. Test subjects entering and leaving the corn oil-charged chamber must be processed in accordance with Section 3.1.2 of this STP and not adversely affect chamber test conditions in between trials. Chamber concentration is required to be monitored continuously and compliant during the entire conduct of each individual LRPL test.

5.5. LRPL Exercises. The LRPL test consists of a set of eleven standard exercises that use eight (8) basic US Department of Labor, Occupational Safety and Health Administration (OSHA) Quantitative Fit Test (QNFT) exercises plus three (3)* additional QNFT exercises carried over from CBRN SCBA and APR LRPL STP. They are one-minute routines devised to stress the face seal and material integrity of the PAPR while it is worn by a human test subject. The appropriate number of test subjects (based on Appendix A) will successively don, activate, and wear the PAPR into the chamber. During each trial of an LRPL test, each human subject will perform the following eleven exercises for one minute each in the below-listed sequence.**

5.5.1. Normal Breathing: In a normal standing position, with hands to the sides or rear and without talking, the subject shall breathe normally for one minute. A recommended procedure is to inhale through the nose and exhale through the nose at a normal pace. Do not touch any portion of the PAPR, including the PAPR sample line, during any part of the LRPL active test. .

5.5.2. Deep Breathing: In a normal standing position as above, the subject shall breathe slowly and deeply for one minute, being careful not to hyperventilate. A recommended procedure is to inhale deeply through the nose and exhale through the mouth.

5.5.3. Turn Head Side to Side: Standing in place, with arms to side, the subject shall slowly turn head from side to side for one minute between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side. Do not deliberately hit the shoulder with any part of the PAPR while conducting the exercise.

5.5.4. Move Head Up and Down: Standing in place, the subject shall slowly move

head up and down. Starting at level plane, move the head up slowly so the eyes are looking straight up at the ceiling, inhale, and hold for one second. Slowly move down past the horizontal level start point to the end point where the chin just touches the chest. Continue the process until told to stop at the level position.

- 5.5.5. Recite the Rainbow Reading Passage or Equivalent: The subject shall talk out loud while reading a copy of the passage entitled Rainbow Passage. Normal breathing is required. Volume of speaking should be loud enough so as to be understandable by the test facility personnel in the control office. Subject will keep reading the passage until told to stop.
- 5.5.6. Sight a Mock Rifle*. While in normal breathing, pick up the mock half-length rifle sample. Test subjects shoulder the mock rifle in the favored shooting posture shoulder position. Bend the head while keeping the RESPIRATOR fitted so as to allow a realistic sight picture to be attained by placing the cheek unhindered by RESPIRATOR components (such as a canister) as close as possible to the rifle stock and rear sight aperture. Hold the cheek to stock position for one second. While bending the head to attain a modified sight picture, extend the non-shooting arm and hand to simulate holding the remaining stock of a standard rifle. After attaining this posture, drop the arms, while still holding on to the mock rifle, to the side. Continue taking up realistic sight pictures with the mock rifle as described until told to stop or one minute. Place the mock rifle down.
- 5.5.7. Reach for Floor and Ceiling (Modified Bending Over exercise 29CFR1910): While in normal breathing, standing, feet shoulder width apart and at arms length from each test subject, subject bends at the waist as if to touch toes/floor. After touching/reaching fully for the toes/floor, subject comes back up at a normal pace, extending arms fully and reaching for the maximum length of arms to the ceiling direction. Keeping the arms locked, continue the procedure until told to stop or for one minute.
- 5.5.8. On Hands and Knees- Look Side to Side*: Before starting, test subject ensures enough room is available between equipment, sample line and other test subjects. In normal breathing, at a normal pace, drop to all fours and extend the head looking straight out. Starting at the center, move the head to the right or left full extreme and hold for one second. Inhale after that one second while holding the head at the extreme extension. Continue doing this exercise, not hitting the PAPR aggressively, for one minute or told to stop.
- 5.5.9. Facial Grimace: While in normal breathing and standing, the test subject will grimace the face by smiling or frowning. Starting with the mouth closed, create a smile or frown that is physically felt by the test subject while wearing the tested PAPR. It is recommended that smiling and frowning be alternated during the one-minute exercise.
- 5.5.10. Climb the Stairs At Regular Pace*: Test subjects pair off in twos, while in

normal breathing, one test subject of the pair holds the appropriate stair case or ladder while the other test subject climbs up at a normal pace and back down at a normal pace. Upon the first subject completing one repetition of up and down, the second subject climbs while the first subject holds the ladder, if necessary. Continue the cycle until one minute expires or told to stop. Return to the floor standing position. Ensure sample lines are not restricting movement during the climb.

- 5.5.11. Normal Breathing: In a normal standing position with hands to the sides or rear, without talking, the subject shall breathe normally for one minute. A recommended procedure is to inhale through the nose and exhale through the nose at a normal pace. Do not touch any portion of the PAPR during any part of the LRPL active test. Disconnect the sample line as instructed.

* One of three additional emergency response exercises added for CBRN tests.
** Exercises must be done in this sequence, starting with the exercise described in Section 5.5.1 through, and ending with, the exercise described in Section 5.5.11

- 5.6. Each trial consists of one donning, sampling of the breathing zone, and one doffing. Test subjects will don the PAPR and enter the test chamber for testing. At the conclusion of this testing, test subjects will exit from the test chamber, return to the ready line and await further instructions for doffing the PAPR.
- 5.7. After a brief intermission (1-10 minutes) with the PAPR doffed, each test subject will re-don the same PAPR and repeat the actions described in Sections 5.4.6 through 5.6 to complete the second trial of testing.
- 5.8. All comments and observations by test subjects, which are voluntary, will be written on the test data sheet.
- 5.9. If a PAPR is identified as a failure upon trial termination, test facility personnel will conduct failure assessment protocol of the PAPR in two phases. First phase is to inspect the PAPR while it is still donned on the test subject. Second phase is to inspect the PAPR when it is doffed. Post-test failure analysis shall consist of inspection of the test subject's eye to eye lens positioning, head harness positioning, head harness strap twists, oral/nasal cup scrunched up on face, canister not on securely, probe loose, missing or any other case-dependent situations. If noted deficiencies are confirmed with the PAPR being improperly probed, reassign another like, but serviceable PAPR to the test subject and retest for two complete trials. If the PAPR has a serviceable probe but continues to fail, log it as a LRPL failure. Only inspect the probe assembly if test results are flat lined or suddenly go flat lined after successful exercise results are indicated. Probe failures such as ripped PAPR material or inadequate probe sealing areas are cause for reanalysis of the determined probe entry point. In cases where the PAPR cannot be probed successfully by the test facility, manufacturer QNFT kits can be reviewed and considered for use, but only as a last resort.

6. PASS/FAIL CRITERIA

- 6.1. The criterion for conduct of this test is set forth in 42 CFR, Part 84, Subpart G, Section 84.63(a)(c)&(d); Federal Register, Volume 60, Number 110, June 8, 1995 and applicable current PAPR statement of standards in final approved form. Each respirator and respirator component shall, when tested by the applicant and by the Institute, meet the applicable requirements set forth in 42 CFR Part 84, subparts G, I, K, and applicable portions of L, N and KK. All applicable manufacturer's Users Instructions that address seal enhancement kits and other critical seal components/tasks must be clearly depicted in final NIOSH approved documents and present during testing.
- 6.2. Each PAPR seeking a CBRN protection rating will be self donned, worn and doffed by a voluntary human test subject in accordance with the applicant's User's Instructions for two independent trials on the same test subject. Testing will be performed in a controlled laboratory atmosphere containing non-toxic corn oil aerosol at 20-40 mg/m³ and having a Mass Median Aerodynamic Diameter of 0.4 to 0.6 micron. All sampling will be performed in the breathing zone of the PAPR. Each PAPR tested shall demonstrate a measured LRPL level that exceeds the level required to PASS for each trial.
- 6.3. An individual LRPL level is calculated quantitatively by evaluating a test subject properly wearing the respirator and conducting the following eleven (11) exercises in this specified sequence: normal breathing, deep breathing, turn head side to side, move head up and down, reciting the rainbow passage, sighting a mock rifle, reach for the floor and ceiling, rotate head side to side while on hands and knees, facial grimace, climb stairs at regular pace and normal breathing. Each respirator test subject shall not be subjected to any undue discomfort or encumbrance because of the fit, air flow or other form, fit and function features of the respirator under test before, during or after the test period. For each size category in accordance with the applicant's User's Instructions, each cell corresponding to the anthropometric parameter corresponding to PAPR design will be tested. Cells can be either individually or simultaneously tested. An individual test subject must complete two test trials using the same PAPR; in the event that an individual test subject completes only one trial and does not complete the second trial, the LRPL data from the completed first trial will not be considered.
- 6.4. The measured LRPL level for each PAPR, while sampling from the breathing zone, shall be 10,000 for $\geq 95\%$ of trials with the blower operating. Each trial must meet the rated breathing zone requirement for that trial to be considered a passing LRPL result as calculated in accordance with Data Sheet No. 0553 in Appendix C of NIOSH LRPL Procedure No. CET-PAPR-STP-CBRN-0553. Test panels from Appendix B of NIOSH LRPL Procedure No. CET-PAPR-STP-CBRN-0553 are used to determine test subject panel size and corresponding test subject anthropometric criteria. Should an LRPL failure be observed in the measured zone, the entire trial is considered a failure and entered as a failure of LRPL for that trial. Should testing results show less than 95.0% of trials having passing LRPL results at any point in the testing, LRPL testing incident reports must be forwarded to NIOSH immediately along with recommendations for follow on test correction. NIOSH confirms re-test procedures and authorizes one additional run of test subjects that fills the entire anthropometric panel requirements be performed to increase the total number of trials; the total number of trials will then be the sum of trials from the first and second run of subjects.
- 6.5. If testing progresses to the point that the PAPR will pass or fail based upon the results of the tests already completed, and if the test results of those test subjects not yet tested would not

change the pass/fail outcome, testing shall be stopped at that point. Test data sheets that will not have data entered in some fields should be completed by stating "Not tested – not required" in those blank fields.

- 6.6. In addition to the stated requirements, NIOSH/NPPTL reserves the right to require, as a further condition of approval, any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous CBRN atmospheres.
- 6.7. Where it is determined after receipt of an application that additional requirements will be required for approval, the Institute will notify the applicant in writing of these additional requirements, and necessary examinations, inspections, or tests, stating generally the reasons for such requirements, examinations, inspections, or tests.

7. RECORDS/TEST SHEETS

- 7.1. All test data will be recorded on the CBRN PAPR LRPL Test Data Sheets shown in Appendix C.
- 7.2. All videotapes and photographs of the actual test being performed and of the tested equipment shall be maintained in the task file as part of the permanent record.
- 7.3. All equipment failing any portion of this test will be handled as follows:
 - 7.3.1. If the failure occurs on a new certification application, or extension of approval application, the Test Facility Manager (Principal Investigator or designee) will send a test report to the NIOSH and prepare the hardware for return to the manufacturer.
 - 7.3.2. If the failure occurs on hardware examined under an Off-the-Shelf Audit, the hardware will be examined by a laboratory technician for cause. All equipment failing any portion of this test may be sent to the manufacturer for examination and then returned to NIOSH. However, the hardware tested shall be held at the testing laboratory until authorized for release by the Technology Evaluation Branch's Branch Chief, or his designee, following the standard operating procedures outlined in Procedure for Scheduling, and Processing Post-Certification Product Audits, RB-SOP-005-00.
 - 7.3.3. If a PAPR fails the Pass / Fail criteria specified in Section 6.4 of this STP, ensure all measures are taken to ascertain the reason/cause for failure, conduct all post-test inspections in accordance with Para 5.9 of this STP that support the accuracy of the reported failure and provide NIOSH with written Test Incident Reports (TIR), digital photos of assessment and recommendations as required.

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APPENDIX A

LRPL Test Sample Quantities for PAPR with Loose-Fitting Hoods

1. Manufacturers with 3 Facepiece Sizes: 38 test subjects, two replicates, and total 76 data points. The maximum number of test subjects equals the maximum number of facepieces required in the following tariff:

Small size: 10 each

Panel face sizes – Boxes 1, 2, 3, 4; panel size 10 (2 or 3 each size, 10 test subjects, 20 total test trials)

Medium size: 17 each

Panel face sizes – Boxes 3, 4, 5, 6, 7, 8; panel size 17 (2 or 3 each size, 17 test subjects, 34 total test trials)

Large size: 11 each

Panel face sizes – Boxes 7, 8, 9, 10; panel size 11 (2 or 3 each size, 11 test subjects, 22 total test trials)

2. Manufacturers with 2 Facepiece Sizes: 29 test subjects, two replicates, and total 58 data points. The maximum number of test subjects equals the maximum number of facepieces required.

Small / Medium size: 14 each

Panel face sizes 1, 2, 3, 4, 5, 6; panel size 14 (2 or 3 each size, 14 test subjects, 28 total test trials)

Medium / Large size: 15 each

Panel face sizes 5, 6, 7, 8, 9, 10; panel size 15 (2 or 3 each size, 15 test subjects, 30 total test trials)

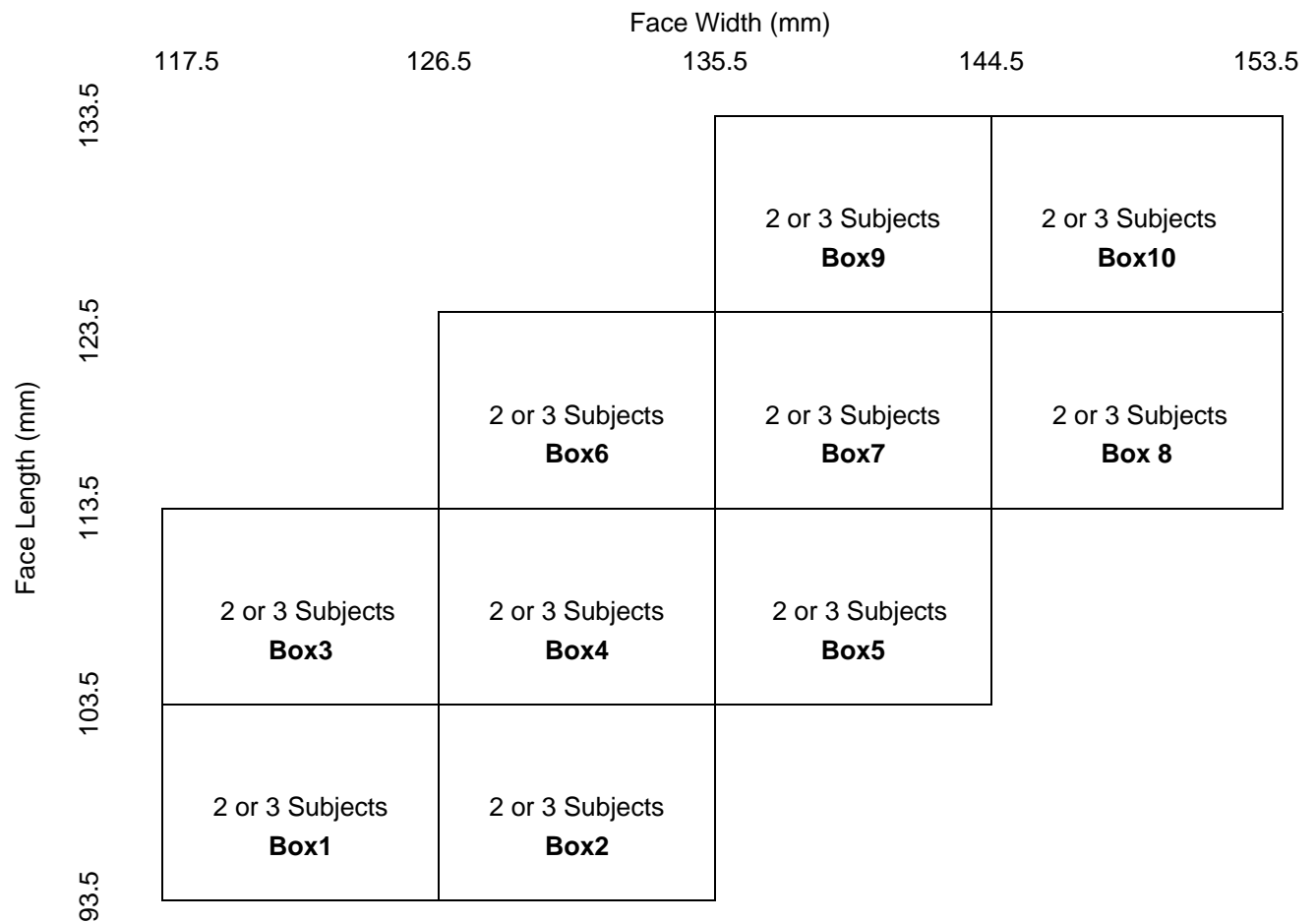
3. Manufacturers with a One-Size-Fits-All Facepiece: 25 test subjects, two replicates, and total 50 data points. The maximum number of test subjects equals the maximum number of facepieces required.

One Size Fits All: 25 each

Panel size – Every Box 1-10; panel size 25 (2 or 3 each size, 25 test subjects, 50 total samples)

NOTES: Some panel members may be the same individuals in a dual role filling the cell requirements of 2 panels for the facepiece sizes. The data for each test subject donning (sample) are judged individually against the pass/fail criteria.

APPENDIX B-1
LRPL Test Panels for PAPR with Loose-Fitting Hood
1 Size



25 Test Subject, One Size/Universal Member Panel for
LRPL Testing of CBRN PAPR with Loose-Fitting Hood

APPENDIX B-2

2 Sizes

		Face Width (mm)				
		117.5	126.5	135.5	144.5	153.5
Face Length (mm)	133.5				2 or 3 Subjects Box9 M/L	2 or 3 Subjects Box10 M/L
	123.5		4 to 6 Total Subjects 2 or 3 Subjects Each Size Box6 S/M or M/L	2 or 3 Subjects Box7 M/L	2 or 3 Subjects Box 8 M/L	
	113.5	2 or 3 Subjects Box3 S/M	2 or 3 Subjects Box4 S/M	4 to 6 Total Subjects 2 or 3 Subjects Each Size Box5 S/M or M/L		
	103.5					
	93.5	2 or 3 Subjects Box1 S/M	2 or 3 Subjects Box2 S/M			

29 Test Subject Member Panel for LRPL

Testing of 2 CBRN PAPR with Loose-Fitting Hood Sizes

Note: 2 size distribution of Small/Medium and Medium/Large is annotated by S/M and M/L, respectively.

APPENDIX B-3

3 Sizes with provisions for 4 and 5 Sizes

		Face Width (mm)				
		117.5	126.5	135.5	144.5	153.5
Face Length (mm)	133.5				2 or 3 Subjects Box 9 L	2 or 3 Subjects Box10 L
	123.5		2 or 3 Subjects Box 6 M	4 to 6 Total Subjects 2 or 3 Subjects Each Size Box 7 M or L	4 to 6 Total Subjects 2 or 3 Subjects Each Size Box 8 M or L	
	113.5	4 to 6 Total Subjects 2 or 3 Subjects Each Size Box 3 S or M	4 to 6 Total Subjects 2 or 3 Subjects Each Size Box 4 S or M	2 or 3 Subjects Box 5 M		
	103.5					
	93.5	2 or 3 Subjects Box 1 S	2 or 3 Subjects Box 2 S			

38 Test Subject Member Panel for LRPL

Testing of 3 CBRN PAPR with Loose-Fitting Hood Sizes

Note: 3 size distribution of Small, Medium and Large is annotated by S, M and L, respectively. For those submissions that contain Extra Small, use Box 1 as an Extra Small (XS). For those submissions that contain Extra Large use Box 10 as an Extra Large (XL).

APPENDIX C

CBRN PAPR LRPL Test Data Sheet (Page 1 of 4)

National Institute for Occupational Safety and Health

Technology Evaluation Branch

Test Data Sheet No.: 0553

**Task No.:**

STP No.: 0553

Manufacturer:

Reference No.: 42 CFR 84.63 (a)(c)(d)

Test: Laboratory Respirator Protection Level Test
for CBRN PAPR

Statement of Standard For CBRN PAPER

Test Date:

Model Number / Trade Name:

PAPR Actual Ready to Use Device Part Number:

Is this a retest under the same TN number?

If yes, what are the original test dates?

Breathing Zone Probe Location:

NIOSH Approval Numbers	

CBRN PAPR LRPL Test Data Sheet (Page 2 of 4)

Temperature:

Relative Humidity:

Respirator Size Quantity:

PAPR Blower On Mode

				TRIAL 1		TRIAL 2	
Test Subject No.	Test Subject Identification	Assigned PAPR Size	LRPL Cell Letter(s)	LRPL value (Breathing Zone)	Enter Pass or Fail	LRPL value (Breathing Zone)	Enter Pass or Fail
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							
21							
22							
23							
24							
25							

CBRN PAPR LRPL Test Data Sheet (Page 3 of 4)

Calculation of % 'Pass' LRPL-PAPR trials

PAPR Blower On Mode

Number of 'Pass' trials from 'Trial 1' column here → _____ (Line 1)
 Number of 'Fail' trials from 'Trial 1' column here → _____ (Line 2)
 Number of 'Pass' trials from 'Trial 2' column here → _____ (Line 3)
 Number of 'Fail' trials from 'Trial 2' column here → _____ (Line 4)
 Add the number of 'Pass' Trials from Line 1 and 3 here → _____ (Line 5)
 Add the number of 'Fail' trials from Line 2 and 4 here → _____ (Line 6)
 Compute the total number of trial by adding Line 5 and 6 here→ _____ (Line 7)

<p>'Overall Pass Percentage Result' here: = (Line 5 ÷ Line 7) X 100%. Enter result here → _____ %</p> <p>Overall Pass Percentage Requirement: ≥ 95%</p> <p>Overall Test Result (Enter 'Pass' or 'Fail') _____</p>

Was all equipment verified to be in calibration throughout all testing? Yes No

Were the part numbers verified against the hardware? Yes No

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CBRN PAPR LRPL Test Data Sheet (Page 4 of 4)

Task No.:	STP No.:	0553
Manufacturer:	Reference No.:	42 CFR 84.63 (a)(c)(d)
Test:	Laboratory Respirator Protection Level Test for CBRN PAPR	
	Statement of Standard For CBRN PAPR	

Comments:

Signature:

Laboratory Technician

Date

Concurrence:

Laboratory Supervisor

Date

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Revision History

Revision	Date	Reason for Revision
0.0	17 November 2006	Original Issue